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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,355	01/31/2005	Robert J. Hariri	9516-149-999	2178

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,355	HARIRI ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-101* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 25-33, and 46-49, drawn to a method of modulating the differentiation of a stem cell, the differentiated stem cell that is the product of the first method, and a method of use of said differentiated stem cell.

Group II, claim(s) 9-16, drawn to a method of modulating the proliferation of a CD34+ or CD133+ progenitor cell.

Group III, claim(s) 17-24, drawn to a method of expanding a population of progenitor cells in a mammalian subject.

Group IV, claim(s) 34-41, drawn to a composition comprising isolated cord and white cells.

Group V, claim(s) 42-45, drawn to a composition comprising CD34+ or CD133+ progenitor cells.

Group VI, claim(s) 50-53, drawn to a method of transplanting mammalian progenitor cells.

Group VII, claim(s) 54-56, drawn to a method of treating an individual experiencing a condition.

Group VIII, claim(s) 57-70, drawn to a method of treating an individual comprising administering white blood cells.

Group IX, claim(s) 71-79, drawn to a method of making a composition comprising contacting CD34+ or CD133+ progenitor cells with the claim-specific compound.

Group X, claim(s) 80, drawn to a product of the process of Group IX.

Group XI, claim(s) 81-89 and 101, drawn to a method of modulating the differentiation of CD34+ or CD133+ progenitor cells.

Group XII, claim(s) 90-101, drawn to a method of producing differentiated cells from CD34+ progenitor cells.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a permissible category of inventions, namely a product, a process specially adapted for the manufacture of said product, and a use of said product. Other methods and products are placed in individual groups, as PCT Rule 13.2 does not provide for multiple methods or products in a single category.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Stem cells I: (a) embryonic stem cell, (b) placental stem cell, (c) cord blood stem cell, (d) peripheral blood stem cell, and (e) bone marrow stem cell, as in claims 3, 26, 48, and 52, for example.

PDE IV inhibitors: (f) SelCID and (g) prodrugs of SelCIDs, as in claims 4, 11, 27, 45, 74, 89, 90, 100, and 101, for example.

Location of differentiation I: (h) cell culture and (i) within an individual, as in claims 5, 6, 12, and 13, for example.

Progenitor cell types I: (j) CD34+ progenitor cell and (k) CD133+ progenitor cell, as in claims 9, 10, 42, 71, and 81, for example.

End point of differentiation: (l) CD34+ CD38-CD33+ cells and (m) CD34+CD38-CD33- cells, as in claims 11, 22, 44, and 88, for example.

Hematopoietic cell types: (n) CD34+ hematopoietic cells, (o) CD38+ hematopoietic cells, and (p) CD11b+ hematopoietic cells, as in claim 33, for example.

Compounds: (q) imide and (r) amide, as in claim 35, for example.

Stem cells II: (s) human stem cell and (t) progenitor cell, as in claims 38 and 39, for example.

Agents: (u) a compound that inhibits PDE IV activity, (v) a stem cell differentiated in the presence of said compound, and (w) a progenitor cell differentiated in the presence of said compound, as in claim 54, for example.

Conditions: (x) inflammation, (y) heart disease, (z) vascular disease, (a') amyotrophic lateral sclerosis, (b') a lysosomal storage disease, and (c') diabetes, as in claim 55, for example.

Location of differentiation II: (d') *in vitro* and (e') in a postpartum perfused placenta, as in claims 58 and 59, for example.

Defects: (f') neutropenia and (g') leucopenia, as in claim 65, for example.

Mode of administration: (h') systemically and (i') intravenously, as in claims 66 and 67, for example.

Cell surface marker characteristics, relative to a control: (j') decrease in CD11c expression, (k') decrease in CD38 expression, (l') decrease in CD80 expression, (m') decrease in CD86 expression, (n') decrease in CD1a expression, (o') decrease in CD14 expression, (p') decrease in $CD54^{bright}$ expression, (q') decrease in HLA-DR expression, (r') increase in CD15 expression, (s') increase in CD33 expression, (t') increase in $CD54^{dim}$ expression, and (u') increase in CD133 expression, as in claim 87, for example.

Progenitor cell types II: (v') dendritic cell, (w') granulocyte, (x') CD34+ CD38- CD33+ cells, (y') CD34+CD38-CD33- cells, and (z') CD34+CD133+ cells, as in claims 94 and 95, for example.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-101.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

lcb

SANDRA E. SAUCIER
PRIMARY EXAMINER